REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary indicates that claims 1-5, 19-34, 40-46, 48, 50-56, and 58-67 are pending in the application. However, Applicants respectfully submit that actually, claims 1-15, 18-34, 36-37, 40-48, and 50-67 are pending. Claims 1-15, 18-34, 36-37, 40-48, and 50-67 were subject to a restriction requirement. On page 2 of the Office Action, the Examiner has acknowledged Applicants' election with traverse and found the traverse persuasive. As a result, claims 6-15, 18, 27, 36-37, 47, and 57 have been withdrawn from consideration, and claims 1-5, 19-26, 28-34, 40-46, 48, 50-56, and 58-67 are under consideration. Claims 1-5, 19-26, 28-34, 40-46, 48, 50-56, and 58-67 stand rejected. Clarification of the Office Action Summary is respectfully requested.

Claim 67 has been amended to recite that the sequence according to claim 1 is operably linked to a second nucleic acid encoding a protein in order to better recite the claimed subject matter.

No prohibited new matter has been introduced by way of the instant amendment. Applicants reserve the right to file a continuation or divisional application on any subject matter that might have been canceled by way of this Amendment.

Regarding the Sequence Listing

A Notice to Comply was attached to the Office Action, requiring a computer readable form and paper copy of the sequence listing, as well as an amendment directing their entry. It is respectfully submitted that this should not be necessary as these items were originally

submitted with the transmittal of the application as shown by the stamped postcard submitted herewith. The PCT Request form PCT/RO/101 dated April 1, 1999 for the present application also indicates that a Sequence Listing was filed with the international application.

Copies of the paper and computer readable forms of the sequence listing that were submitted with the original national stage filing of the application are enclosed herewith together with a declaration under 37 C.F.R. §§ 1.821-825 simply in order to comply with the Notice to Comply. In the event that the Sequence Listing has not previously been entered, its entry is requested.

Rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 1-5, 19-34, 40-46, 48, 50-56, and 58-67 have been indicated as rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. The Examiner has asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is respectfully traversed.

It is also noted that the rejection appears to include claim 27, which has been indicated as having been withdrawn from consideration at page 2 of the Office Action. Thus, it is assumed that inclusion of claim 27 in the listing of rejected claims was inadvertent and claim 27 is, in fact, not rejected. Clarification of the record is respectfully requested.

The present rejection is not proper under the *Guidelines for Examination under the 35 U.S.C. § 112, paragraph 1, "Written Description" Requirement*, which have been promulgated by the Office in the Federal Register (66 FR 1099, January 5, 2001) and incorporated into the Manual of Patent Examining Procedure (M.P.E.P.) at § 2163. Under

the law, the Office has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). The M.P.E.P. introduces the methodology for determining adequacy of written description as follows:

> The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, [*In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (CCPA 1976).] . . . Consequently, rejection of an original claim for lack of written description should be rare. M.P.E.P. § 2163(II)(A)

The Examiner has failed to meet the initial burden that the law requires. The Examiner must present evidence or reasons, not mere conclusory allegations, why one skilled in the art would not recognize that the inventors were in possession of the claimed invention at the time the application was filed. That burden has not been met.

Claim construction is the first and essential step in the process, and the claims must be construed as a whole. The M.P.E.P. states:

> Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). The entire claim must be considered, including the preamble language and the transitional phrase. "Preamble language" is that language in a claim appearing before the transitional phase, e.g., before "comprising," "consisting essentially of," or "consisting of." The transitional term "comprising" (and other comparable terms, e.g., "containing," and "including") is "open-ended" -it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves the "claim open for the inclusion of unspecified ingredients even in major amounts"). M.P.E.P. § 2163(II)(A)(1) (emphasis added).

A thorough reading and evaluation of the content of the application is also required. The M.P.E.P. further states:

> Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. M.P.E.P. § 2163(II)(A)(2).

The Examiner has construed the claims as follows: "The invention of the instant claims is drawn to a complementary strands (*sic*) of nucleotides 1-740 of SEQ ID NO:1, which includes any sequence of any length so long as it is complementary to nucleotides 1-740 of SEQ ID NO: 1." Office Action at 4. However, claim 1 actually recites: "An isolated nucleic acid comprising a promoter for the expression of recombinant proteins in filamentous fungi that comprises a nucleotide sequence or a complementary strand thereof, having nucleotides 1-740 of SEQ ID NO:1." Thus, claim 1 is directed to a promoter for the expression of recombinant proteins in filamentous fungi comprising nucleotides 1-740 of SEQ ID NO:1 and/or the complement thereof (it being well understood that in various embodiments and at various stages of use or manipulation, a nucleic acid can be single or double-stranded).

One skilled in the art would immediately appreciate that a promoter sequence as claimed here would be most often used in a nucleotide molecule in combination with other sequences; for example, a sequence coding for any protein of interest combined with other elements of an expression system, both those described in the specification and such elements that are conventional in the art. Thus, the use of open language permitting the inclusion of unspecified additional elements in the nucleotides of the instant claims is entirely appropriate to fully describe the claimed promoter as it will be found in its normal usage.

The specification provides ample description of the claimed invention. For example at page 2, "[t]he invention provides a new expression system that makes use of the promoter from the glutamate dehydrogenase gene from filamentous fungi of the genus *Aspergillus*. . ." At page 3, the subject matter of claim 1 is described almost word-for-word, with particular identification of nucleotides 1-740 of SEQ ID NO:1 as the promoter of the glutamate dehydrogenase A (*gdhA*) gene from *Aspergillus awamori*.

The Examiner states that "[t]hese are genus claims that encompass a wide array of sequences." And the Examiner alleges that "[t]he specification does not disclose what these many complementary sequences may be and also the specification and [*sic*] does it provide any teaching as to how the structures of these sequences relate to their function." This allegation is clearly in error.

The Specification thoroughly describes the use of this promoter in various fusion constructs to express a protein of interest and to directly express a protein of interest, for example at pages 5-8 of the specification. At page 8, from line 9, the specification describes a non-limiting list of various additional elements that one skilled in the art would immediately appreciate may be included in an expression construct comprising the claimed promoter.

At page 4 of the Office Action, claims 21, 22, and 23 are specifically addressed as being drawn to the proteins recited therein. For example, claim 21 is construed as follows: "The invention of claim 21 is drawn to glucoamylase or a portion thereof." It has been further alleged that claims 21, 22, and 23 "are drawn to undefined portions or fragments of the proteins for which the specification has failed to provide adequate description."

However, incorporating the subject matter of parent claims 1, 19, and 20, claim 21 actually recites:

> 21. A DNA construct that comprises: a) a promoter from a glutamate dehydrogenase gene from a fungus of the genus *Aspergillus*; b) a DNA sequence encoding a protein expressed from a filamentous fungus or a portion thereof; c) a DNA sequence encoding a cleavable linker peptide; and d) a DNA sequence encoding a desired protein,
>
> wherein the promoter under a) is a promoter for the expression of recombinant proteins in filamentous fungi that comprises a nucleotide sequence or a complementary strand thereof, having nucleotides 1-740 of SEQ ID NO:1,
>
> and wherein the DNA sequence under b) encodes a protein or portion thereof selected from the group consisting of: i) glucoamylase from *Aspergillus awamori, Aspergillus niger, Aspergillus oryzae,* or *Aspergillus sojae*; ii) B2 from *Acremonium chrysogenum*; and iii) a glutamate dehydrogenase from a filamentous fungus,
>
> and wherein the DNA sequence of b) encodes a glucoamylase from *Aspergillus awamori, Aspergillus niger, Aspergillus oryzae* or *Aspergillus sojae,* or a portion thereof.

Thus, claim 21 is not drawn to "glucoamylase or a portion thereof" as alleged. Rather is drawn to a DNA construct which is a fusion expression construct comprising a DNA sequence encoding glucoamylase or a portion thereof, as described in detail in the specification, for example at pages 6-7. Claims 22 and 23 likewise describe particular embodiments of the fusion expression constructs that are described in the specification.

One skilled in the art would recognize that fusion constructs are used to assist in expression and folding of a protein of interest as pointed out at page 2 of the specification. The recited DNA sequence encoding glucoamylase or portion thereof is in the position of a carrier protein as described in the specification. As the use of fusion constructs in general was known in the art, one skilled in the art would understand the structural and functional parameters of the sequence encoding the carrier protein.

It is not necessary to describe what is known or conventional in the art. The M.P.E.P. states:

> The description need only describe in detail that which is new or not conventional. See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 U.S.P.Q. at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 U.S.P.Q.2d at 1805 (source code description not required). This is equally true whether the claimed invention is directed to a product or a process. M.P.E.P. § 2163(II)(A)(3)(a).

The Specification provides ample description of the novel and unobvious subject matter recited in the claims. The skilled practitioner is well aware of additional elements that could be conventionally included in a nucleic acid comprising the promoter of claim 1, whether in a replication vector, an expression vector, or as an intermediate product used in the process of making such a construct.

For at least the foregoing reasons, one skilled in the art would have appreciated that the inventors were in possession of the full scope of the claimed invention at the time the application was filed. Accordingly, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph, enablement

Claims 26 and 66 stand rejected under the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner has asserted that biological deposits are necessary satisfy the enablement requirement for these claims. The rejection is respectfully traversed.

Claim 26 recites the DNA construct according to claim 25, wherein the DNA sequence of d) is the thaumatin II synthetic gene from plasmid pThIX. At page 7, line 27, the specification teaches that plasmid pThIX is described in published European patent application EP 684312, which was also cited in the International Search Report of the Application and the Information Disclosure Statement, filed October 2, 2000. Applicants also note that the starting materials and steps taken in making plasmid pThIX are described in detail in U.S. Patent No. 5,932,438, see for example in Figure 13.

Accordingly, under 37 C.F.R. § 1.802(b) there is no need for a deposit in this case in order to satisfy the enablement requirement with respect to claim 26.

> Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, *inter alia*, if it is known and

> readily available to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons. 37 C.F.R. § 1.802(b)(emphasis added).

Claim 66 recites the filamentous fungi strain of claim 65, wherein the strain is TGDTh-4 with Access No. CECT20241. At page 37, lines 28-32, the specification describes the deposit of this strain according to the Budapest Treaty in the Colección Española de Cultivos Tipos (CECT) on March 25, 1998. A copy of the deposit receipt is attached hereto. Thus, the biological material referred to in claim 66 has, in fact, been deposited.

In view of the foregoing, withdrawal of the rejections is respectfully requested

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL PC
INCLUDING ATTORNEYS FROM BURNS DOANE SWECKER AND MATHIS LLP

Date: November 2, 2005

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